UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF NEW YORK

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JOSEPH BARONE) 17cv6877
)
vs.
Rochester, New York
BAUSCH & LOMB INC, MORCHER GmbH, and FCI OPHATHALMICS, INC
August 27, 2018
Defendant.) 4:00 p.m.
- - - - - - - - - - - - - - - - X

MOTION HEARING

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE ELIZABETH A. WOLFORD
UNITED STATES DISTRICT JUDGE

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BARONE VS. BAUSCH & LOMB, ET AL

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P R O C E E D I N G S

* * *

THE CLERK: The Court calls the matter of Barone vs. Bausch & Lomb, Inc. 17CV6877.

THE COURT: Good afternoon. Mr. Lipari, am I pronouncing it correctly?

MR. LIPARI: It is Lipari.

THE COURT: I was not pronouncing it correctly.

MR. LIPARI: Your Honor was close enough.

THE COURT: Lipari.

MR. LIPARI: Lipari. The family name is Lipari.

THE COURT: Lipari. Hopefully I'll stick with that. Nice to meet you.

MR. LIPARI: Nice to meet you.

BARONE VS. BAUSCH & LOMB, ET AL

THE COURT: On behalf of Bausch & Lomb?

MR. SMULIAN: Smulian, Daniel Smulian.

THE COURT: Nice to meet you.

MR. SMULIAN: Nice to meet you, Judge.

THE COURT: And on behalf of Morcher, GmbH?

MR. VONWALDOW: Arnie VonWaldow.

THE COURT: How do you pronounce the last name?

MR. VONWALDOW: VonWaldow.

THE COURT: Nice to meet you.

MR. VONWALDOW: Nice to meet you.

THE COURT: Mr. Paulino is here on behalf of FCI Op?

MR. PAULINO: Opthalmics.

THE COURT: Opthalmics. Mr. Paulino and Mr. VonWaldow do not have a motion pending. It is B & L's motion to dismiss. You can stay seated at counsel's table and you can stay seated. You don't have to stand for oral argument. If you prefer to stand at the podiums, you can do that, but it may be easier to stay at the tables. The reason I'm saying to stay seated, when you're standing, you're further away from the microphone, sometimes more difficult to hear.

Let me start off, it's Bausch & Lomb's motion and I want to hear your arguments and hear from the Plaintiff. Let me start out with a question I have to both parties, which is,

and it wasn't raised, I'm not so sure I have jurisdiction. I know there was a Notice of Removal that was based on the fact or the allegation that substantial question of federal law are involved. But when I went and looked at the cases, it seems as though there are cases in our circuit that reached some different conclusions as to whether or not there was preemption. They were all based on diversity. And there are no allegations of diversity jurisdiction here. Essentially because of the offense of preemption or, as I understand it, or perhaps because of the allegations that the failure to warn was based on the failure to warn is required under federal law, Bausch & Lomb is alleging that there is a substantial question of federal law. But I'm not so sure the case law would support you on that because it's a New York State cause of action that is --

MR. SMULIAN: It is a New York State cause of action, your Honor. It is our position that there is a substantial issue of federal law because the state law claim requires looking at -- it is based on the reporting of -- the federal reporting statutes. And there are cases -- I apologize, your Honor, I don't have my moving papers.

THE COURT: And quite frankly, if I had been more proactive in this, I would have notified everyone of this issue. I'm not going to hold you to anything that is said here

today. But I think that is an initial inquiry that I have to get through. I've done some research on it, my law clerks have done some research on it. And I have significant concerns over whether or not I have subject matter jurisdiction. I'll give you a couple of cites. If you can just bear with me for a moment. And obviously, I appreciate the fact that the Plaintiff has not raised this issue, but subject matter jurisdiction, of course, is not something that can be waived. The one in our district or our circuit that I thought was the most on point was a Connecticut case. It's *Mihok*, M-i-h-o-k, *vs. Medtronics, Inc.*, the cite is 119 F. Supp. 3d 22, District of Connecticut from 2015. Where the Court construed the *Gunn-Grable* substantiality aspect of whether or not there is jurisdiction in a circumstance like this is requiring the construction and validity of a federal statute conduct by the government under that law and whether the conduct is permissible. And it found that the limited fact-specific application of FDA regulations was not substantial.

MR. SMULIAN: Just from memory, Judge, I know that the *Bowdrie* versus -- *Bowdrie vs. Sun Pharmaceuticals*, I don't have the cite in my head, but that was a case in the Eastern District of New York. I suspect that it's in our Notice of Removal. I would submit that that case is directly on point and in the context of at least drugs and devices. Also, I

think, if I recall correctly, there is a case named *D'Allessio vs. New York Stock Exchange*, it's a Second Circuit case. It's not in the drug and device context, but it is, I think, it speaks to the issue of --

THE COURT: You cited *D'Allessio* in the Notice of Removal.

MR. SMULIAN: Okay.

THE COURT: But I'm not seeing --

MR. SMULIAN: Not seeing *Bowdrie?*

THE COURT: No. I'm looking at it real quick, but, no, you do have it here. I can take a closer look at that. You have it at paragraph 26 of your Removal. I'm going to want further briefing on this because, I mean, the fact, the question of federal law is just the fact that you're claiming it preempts.

MR. SMULIAN: Respectfully, Judge, I think that the Plaintiff invoked federal law in their complaint.

THE COURT: But the New York State causes of action --

MR. SMULIAN: But under --

THE COURT: Let me finish. Don't interrupt me. Rule of this Court, you interrupt me, you're going to annoy me. The fact of the matter is, there is state law causes of action that are based on a requirement under federal law, but there

are still state law causes of action.

MR. SMULIAN: That's true, Judge. But under *Grable,* and I think under the cases -- under *Bowdrie*, under *D'Allessio*, I think you can still have a state law cause of action when --

THE COURT: And that that would satisfy the substantial invocation of federal law?

MR. SMULIAN: Yes, Judge, I think you can. And I would be happy to brief it further. And I look forward to that opportunity.

THE COURT: But it still is -- I mean, in other words, even if -- and I appreciate Bausch & Lomb has made a motion to dismiss. But even if there was a requirement under federal law that could serve as a basis for a state law claim, it still is the state law claim, the state law remedy that is being pursued here.

MR. SMULIAN: It is. And I think this was exactly the issue in *Bowdrie* in the case in the Eastern District. It was state law, it was a drug case, not a medical device case, so the regulatory theory was slightly different, but similar enough for, I think, these purposes. And it was a failure to warn cause of action that was asserted against the Defendant drug manufacturer, a state law cause of action, but it relied on allegations related to federal law in connection with the

Defendant manufacturer's ability to change the label on its own as opposed to going to the FDA to seek permission. And so it was a state law cause of action where the duty, I mean, the claim turned on whether federal law permitted -- what federal law required. And so the court in that case found that there was a substantial question of federal law even though there is the cause of action is a state law cause of action and retained jurisdiction. And then, in response to the motion to dismiss in that case, granted the motion to dismiss.

THE COURT: Okay. Does Plaintiff's counsel have a position on this that you're able to articulate right now?

MR. LIPARI: Well, the question is right now. No, your Honor. I mean, Plaintiff certainly agrees with your Honor's characterization of the complaint. These are all state law claims and is the question, is it a substantial implication of federal law. Plaintiff doesn't -- I don't want to paraphrase cases that I don't have before me. And I think we would like the opportunity, if your Honor so chooses, to perhaps put in some supplemental briefing on this issue.

THE COURT: Okay. We'll set a schedule after we hear oral argument on the pending motion to dismiss on that issue as well, because I'm going to have to get through that before and if we get to the other issues. With that being said, I appreciate that it's your motion, so why don't you go

ahead?

MR. SMULIAN: Thank you, Judge. As I introduced myself, my name is Daniel Smulian on behalf of Bausch & Lomb. We're here on Bausch & Lomb's motion to dismiss. I don't know if there is a particular place you would like me to --

THE COURT: It struck me that -- I appreciate there are cases dealing with the express preemption issue, which is your first argument. It strikes me that the Northern District case that is cited in the papers says -- reaches one conclusion, and then there are some other cases in this district reaching another conclusion. It does seem as though there is a split in authority. Would you agree with that?

MR. SMULIAN: I would agree with that, Judge. I think the weight of authority in districts within the Second Circuit favors our position. But certainly the Northern District case in *Rosen* comes out in Plaintiff's direction, whereas *Pearsall*, in the Eastern District, comes out in our direction. I think *Pearsall* is fortified by a decision called *Ilarraza vs. Medtronic*s, also an Eastern District case. It's slightly different because it involves good manufacturing practice regulations, but it sort of indicates the cases upon which *Rosen* relies -- so, I think, *Rosen* relies on *Stengel*, *Rosen* relies on *Hughes*, primarily. Both of those cases are sort of disfavored by the cases in -- by *Pearsall* and by other

cases in this district. So, you know, I think when you look at what the cases say, when you look at *Stengel*, for example, *Stengel* is a Ninth Circuit case applying Arizona law. And it found that under Arizona law, Arizona law contemplates a duty to warn third parties, which in the Ninth Circuit's interpretation, they found was sufficient to parallel a duty to provide adverse event reports to the FDA. In *Hughes*, which is a Fifth Circuit decision, the Court -- and Judge Wexler, in *Pearsall,* specifically noted this -- that the Mississippi statute encompassed a reporting requirement regarding adverse events and malfunctions.

You know, I think what Judge Pearsall or what Judge Wexler in *Pearsall* said, New York simply doesn't have the requirements that -- the requirement that the *Stengel* court found for Arizona, and that the *Hughes* court went for Mississippi. That New York has a duty to provide warnings to physicians. And I think there is a fundamental --

THE COURT: And you think because -- and I want to hear from Plaintiff's counsel, obviously -- but if I'm understanding the Plaintiff's argument, it's that the duty to provide a warning to the FDA would necessarily then result in a warning to a physician, and therefore, that is a parallel claim under state law that is being made here. You can argue with the factual basis for that, but, I mean --

MR. SMULIAN: I'm trying to see if that conceptually matches how I look at this, Judge. The way I would say it is, the Plaintiff alleges that everyone acknowledges that there is a duty to report to the FDA under federal reporting statutes. I think the Plaintiff argues that the New York duty to warn encompasses, you know, it encompasses that duty. And I would submit that it does not. That the duty to warn that exists under New York common law, because there isn't a products liability statute like there is, for example, in Mississippi, is a duty to provide adequate warnings to the user, which in the case of prescription medical devices is the physician. And particularly, in the context of one of the cases we cited, *Aaron vs. Medtronics*, I think, makes this clear that the warnings that are provided to physicians in the form of device labeling. That is how manufacturers provide warnings to physicians. That is a very different thing. Warnings -- adverse event reports are not warnings. So, I think I look at the way that Judge Wexler in *Pearsall* sort of said, look, there is a duty to provide warnings and that there is a duty to provide adverse event reports to the Food and Drug Administration, and those are not the same thing, and, therefore, they are not parallel. Because when you look at -- when you start with the governing framework, so section 360K(a) of Medical Device Amendments to the Food, Drug, and Cosmetic

Act and there is an express preemption clause and that express preemption clause says that no state or political subdivision can impose requirements that are different from or in addition to the federal requirements. So when you look at the cases and you figure out what that means, it means that the state -- in order for a claim to be parallel, it means that the state law duty -- and the cases use different words -- but either has to be identical or genuinely equivalent or the same. So --

THE COURT: Or it can't add any additional requirement.

MR. SMULIAN: It can't add any additional thing. And so that is why in *Pearsall*, the Court held that the federal -- I'm quoting here -- "The federal requirements require that adverse events and other reports be made to FDA. While New York law may require New York manufacturers to warn the medical profession, that is not the same as a duty to report to FDA. Thus, since the state law duty imposes obligations that are different from or in addition to the federal requirement, the court finds that the Plaintiff's failure to warn claim is preempted." *Pearsall* is hardly alone in finding that the duty of a particular state isn't parallel to the federal reporting requirements. So *Aaron v. Medtronic*s is an Ohio case, it's cited in our brief. And it functionally says the same thing, and goes onto say, you know, "Doctors are warned of the risks

of the medical device through the device's labeling, not through adverse event reports submitted to the FDA." And the reason that is important is because the Plaintiffs haven't and can't allege that certain warnings weren't provided to the labeling. That is the very essence of a preemptive claim under *Riegel*, because the FDA prescribed -- the FDA approved the device pursuant to the PMA process, and set the content of the labeling. And it can't be changed in the absence of a supplementary PMA application. So that is the reason that Plaintiffs -- the Plaintiff hasn't alleged that there is a problem with the labeling itself. This is an end run around the labeling by saying, well, you didn't submit adverse event reports.

THE COURT: Explain to me your argument about implied preemption. I mean, in other words, this is just an alternative argument, or, I guess, and I was having a little trouble understanding why, if there is an express preemption, why would there also then be implied preemption?

MR. SMULIAN: I think the implied preemption, the way I look at it is a sort of the flip side of the same coin of preemption, and so when you look at certain decisions, courts sometimes find both express and implied, and sometimes courts render a decision to a failure, an alleged failure to make adverse event reports under implied preemption. I guess it's

both an alternative -- and, I mean, it stands on its own, I think, as you see in some cases that we've cited, but it also is -- it joins the express preemption. I mean, the idea is that the Food, Drug, and Cosmetic Act, there is no private right of action under the Food, Drug, and Cosmetic Act. So what the Supreme Court explained in *Buckman* is that, and I'm quoting, "The FDC leaves no doubt, it is the federal government rather than private litigants who are authorized to file suit for noncompliance." And so in subsequent decisions in the Eighth Circuit decision in *In Re Medtronics vs. Sprint Fidelis*, 623 F. 3d 1200, in 2010, it held that a claim that a manufacturer failed to file an adverse event report is merely an attempt by a private party to enforce the MDA, the Medical Device Amendments, and those are closed by Section 337 as construed by *Buckman*. There is this quote that you see in a lot of these -- in a lot of the briefs from a case called *Riley vs. Cordis*, and it's a difficult quote conceptually, but I keep going back to it. And the quote is, "To avoid implied preemption, the Plaintiff must be suing for conduct that violates the FDCA, but the Plaintiff must not be suing because the conduct violates the FDCA." So it sort of, it's the nature of a parallel non-impliedly preempted claim. And I think *Riley* said also one thing that is particularly important here, and it says, and I'm quoting "The conduct on which the claim is

premised must be the type of conduct that would traditionally give rise to liability under state law and that would give rise to liability under state law even if the FDCA had never been enacted. If the Defendant's conduct is not of this right and then the Plaintiff is suing of a violation of the FDCA, no matter how the Plaintiff labels the claim, and that Plaintiff's claim is, therefore, impliedly preempted." So here the claim, as asserted by the Plaintiff, is not directed to the type of conduct that would traditionally be a basis for a claim even if the FDCA had never been enacted. I mean, so as the Court explained in *Pinsonneault*, which is another case we cited in our brief, "The failure to properly or timely warn the FDA via the NDR process as opposed to warning a doctor or patient of a device is dangerous, it is not a type of conduct that would give rise to liability even if the FDCA had never been enacted." So --

THE COURT: Is your point that in order for, if, in fact, the Plaintiff was truly alleging what the Plaintiff is claiming its alleging or is alleging, that this is a state law claim based on failure to warn, to provide notice to his physician that would have prevented the injuries that he suffered here, that if that was, in fact, what was being alleged and it isn't expressly preempted, it must necessarily be implicitly preempted because he is really trying to bring a

claim that is the exact claim as to what is required under federal law? I mean, in other words -- go ahead.

MR. SMULIAN: That he is trying to -- our position would be that the Plaintiff is trying to enforce the Food, Drug, and Cosmetic Act.

THE COURT: And if he isn't doing that, then the Food, Drug, and Cosmetic Act preempts his claim. And if he is doing it, he doesn't have standing to do it and it's implicitly preempted because he can't bring a claim under federal law?

MR. SMULIAN: That's right. And all of this goes back, there is no New York State law duty to warn the FDA.

THE COURT: And if there was, then it may be a different argument at least on express preemption?

MR. SMULIAN: That's right, your Honor. Now, once you get past expressed and implied preemption.

THE COURT: I think your causation argument is a descent argument. I just have concerns about dealing with that argument on a motion to dismiss 12(b)(6). I mean, I think there is a lot of case law that suggests that causation is often a fact issue or a question of fact, causation is alleged here. I know your argument is it's not plausible that the failure to warn the FDA that --

MR. SMULIAN: That's right. And there is one, I guess, additional point I wanted to make as I was getting ready

for the argument that as I thought about it more. The surgery in this case, the Plaintiff's surgery occurred in 2015. The only alleged underreporting occurred in 2008 and 2009. There is no alleged underreporting that occurred in 2010, and there is no alleged underreporting that occurred in 2011, '12, '13 or '14 or the first half of '15 because the surgery was in August. I submit that it's implausible that the doctor -- that the Plaintiff's physician allegedly relied upon information and belief on alleged underreporting from between six and seven years prior to the surgery at issue in this case. I don't think that makes -- putting everything else aside, I don't think that makes sense. I think there is an issue with the fact that the allegation regarding the doctor's alleged reliance is made on information and belief. I think that there are cases, and they are cited in our brief, that speak to the fact that if you're going to make a critical allegation on information and belief, then you have to identify the information or facts that give rise to that belief. But, putting that aside, I think when you look at the cases -- Plaintiff cites a case called *Michajlun*. It's spelled M-i-c-h-a-j-l-u-n. And in *Michajlun*, the issue in that case was in 2012. And to be perfectly candid, your Honor, the Plaintiff has lifted his allegations in this case from the allegations in *Michajlun*. If you compare the factual

allegations in the *Michajlun* decision to the complaint, the amended complaint in this case, they are identical. But in *Michajlun*, the Defendant raised the causation issue, and the Court said -- the Court said, well, you know, it's admittedly thin that in 2012, a surgery going back to the 2008 and 2009 alleged underreporting and adverse events, and I admit it's thin, but I'll let it go. I'll let the claim proceed. You know, this is now over three years -- the facts in this case are over three years later. The surgery is over three years later. If *Michajlun* was thin, was admittedly thin by a court construing California law, which, also, like Mississippi, has its own statutory corollary for federal law, but if a court construed the case in *Michajlun* that that was thin on causation but let it proceed, this case, I mean, this case is thin to the point of breaking in terms of it being plausible. It's just the idea -- I have made my point. I don't need to keep reiterating. I think the idea that a doctor in 2015 is going to go back to the -- also, we didn't talk about the fact that there are four alleged reports, according to the Plaintiff, that were not made in 2008 and 2009. I don't, just for the avoidance of doubt, we don't concede that there is any underreporting, but, again, accepting the allegations as true, it isn't plausible that the Plaintiff's physician in 2015 relied on -- that four non reports in 2008 and 2009 were what

made his decision.

The only other thing that I just wanted to quickly address -- well, two things. One, woven into Plaintiff's amended complaint are allegations that seem to say that Bausch & Lomb breached a duty to warn Plaintiff directly. I can't tell if that is really intentional. But New York has the learned intermediary doctrine that provides that a manufacturer of medical devices, prescription medical devices, owes a duty to warn the physician, not the Plaintiff. So to the extent that Plaintiff's claim is that we failed to warn him, I would submit that claim needs to be dismissed because of the learned intermediary doctrine.

The only other thing I would say is there are sort of theoretical cross claims of FCI against Bausch & Lomb and Morcher, I say, theoretically, it's hard to tell whether they are an actual cross claim or affirmative defense. I submit those should be extinguished if our liability to the Plaintiff is extinguished based, you know --

THE COURT: There is no so-called cross claim asserted in the answers by your codefendants, are there or there are not? They are shaking their head no.

MR. SMULIAN: Okay. Then in that -- so maybe it's just an affirmative defense and we don't have to worry about it. It's styled as an affirmative defense and also a cross

claim. I wanted to say, to the extent it's an actual cross claim --

THE COURT: I guess I didn't see that. Are there cross claims?

MR. SMULIAN: I mean --

THE COURT: If the affirmative defense is based on a codefendant's alleged culpability or liability, that doesn't make it a cross claim.

MR. SMULIAN: It's just, it's styled -- it's styled both as an affirmative defense and as a cross claim and it's for indemnification and contribution, so it is in FCI's answer.

THE COURT: I'm looking at that. Well, I guess the answer was filed in state court. I'm looking at FCI and Morcher's answers right now. And it does say "and cross claim against codefendants."

MR. SMULIAN: And, your Honor --

THE COURT: Just so the record is clear, I'm looking at FCI's answer, which in its sixteenth affirmative defense asserts a cross claim "failure to join in necessary party." And then cross claim for contribution. Your point is --

MR. SMULIAN: My point is if that is actually a cross claim as opposed to an affirmative defense, that it

should go away, too, if your Honor grants our motion to dismiss.

THE COURT: It doesn't look like Morcher's answer has the affirmative defense characterized as cross claims, it's FCI. I guess, Mr. Paulino, let me ask you, since you represent FCI. Would you agree with that point, that if, in fact, Bausch & Lomb's motion to dismiss is granted, that it's out of the case or would FCI be taking the position that somehow it has a separate --

MR. PAULINO: I guess --

THE COURT: Make sure your microphone is on there.

MR. PAULINO: It's not part of the motion that we sought. I apologize, I'm not prepared to argue it. We didn't brief it or think it through. We would have the contribution law under New York claims. If there are New York claims that exist against them, we would have the affirmative defense under New York law to say another party is culpable, whether they are in the New York claim, our contribution claim would be independent of whether or not the Plaintiff's causes of action may or may not stay. If Plaintiff doesn't sue someone, it's not going to prevent my client from bringing a contribution claim against them.

THE COURT: I guess the point is that if, in fact, Bausch & Lomb's motion to dismiss is granted, that doesn't act

as a bar with prejudice for any contribution or indemnification claim to be asserted by either one of the Defendants in the event that you have some kind of liability to the Plaintiff. I mean, Bausch & Lomb can certainly argue against it, but I don't think -- it hasn't been briefed to me.

MR. SMULIAN: That's right.

MR. PAULINO: No. I would just say, your Honor, it's not part of the motion and I don't believe they are requesting that relief, to the best of my knowledge. To your Honor's point, our contribution claims, under New York law, have nothing to do with Plaintiff's claims against Bausch & Lomb.

THE COURT: Right. In other words, well, a codefendant could have a claim against Bausch & Lomb for the faulty device. I mean, but it's not based on the failure to warn that the Plaintiff is suing -- I mean, there could be a contractual contribution claim, I don't know if there is. That wasn't raised in the motion.

MR. SMULIAN: Correct. I was just thought I was clarifying our position, but I guess it's something we can take up with FCI. There is nothing -- assuming that for the sake of argument that your Honor grants our motion to dismiss, assuming that FCI -- we will then have to make a motion to dismiss.

THE COURT: I guess the question is, would Bausch

& Lomb still be part of the case by virtue of the cross claim that has been asserted by an affirmative defense?

MR. SMULIAN: Right, because there is no cross claim that would give allegations to liability. You're right, it's not briefed. But, I just wanted to sort of put our position down, which is that we will brief, if necessary, that if we get out of the case as to the Plaintiff's claims, I don't see a basis for holding us in the case based on the affirmative defense that is in that answer.

THE COURT: All right. Well --

MR. PAULINO: Just to clarify, your Honor. That relief was not requested in the motion, so it's not an issue that is pending before the Court; is that correct?

THE COURT: Right, that is correct. So let me hear -- were you finished?

MR. SMULIAN: Yes, Judge.

THE COURT: Let me hear from Mr. Lipari. And I guess my first question is, how do you reconcile the express preemption? I mean, federal law has a duty to warn the FDA through adverse event reporting, and how does that possibly get transformed into a duty to warn under New York State law the medical provider? How is that possibly parallel?

MR. LIPARI: Your Honor, we would submit that Judge Wexler simply got it wrong in the *Pearsall* decision and

the *Rosen* decision was right, and that is for a few reasons. First of all, in the *Rosen* decision, the Court recognized that given the FDA's publication of adverse events through the MAUDE system, which is arguably one of the reasons that reporting is required in the first place, that a failure to report to the FDA essentially amounts to a failure to report to and warn the medical community, and therefore, the state and federal requirements are parallel. Judge Wexler in the *Pearsall* case didn't engage in the analysis and didn't grapple with the issue of MAUDE and the impact or effect of MAUDE. Where, in effect, the *Rosen* decision, an analysis of the MAUDE database was crucial. I'll say this, in the *Rosen* decision, and this is unlike the *Pearsall* decision --

THE COURT: The MAUDE analysis was undertaken with respect to the express preemption in *Rosen?*

MR. LIPARI: Correct, your Honor. Well, your Honor, so the Court talks about MAUDE generally, and then seems to indicate that, given that New York law imposes a continual obligation -- and I'll back up and talk about where the continuing obligation is articulated in the body of cases -- but the exercise of reasonable care and warning of potential dangers through the reporting essentially allows that manufacturer to discharge his duty or, rather, its duty. And I could point to the MAUDE-related language if that is what your

Honor is specifically calling for.

THE COURT: Sure. I mean, I am looking at page 184 through 185 of the *Rosen* decision, which is a discussion of express preemption, and I don't see a reference to it. I see the Court is essentially relying on the *Hughes* decision from the Fifth Circuit, and the *Medtronics* decision from the Ninth Circuit, and then discussing why those cases are not not applicable.

MR. LIPARI: Well, your Honor, later on in the decision, and it's right above --

THE COURT: And do you have a page number?

MR. LIPARI: I'm not sure, your Honor. It looks like it's three paragraphs above the conclusion.

THE COURT: MAUDE, all capitalized.

MR. LIPARI: Correct, your Honor.

THE COURT: So, page 187, that is in the discussion of causation.

MR. LIPARI: Well, that's true, your Honor, but it's tied back in terms of -- so, I have, your Honor, I have page 19 of 22. And I can give you -- let me try to give you a pin cite, your Honor. It looks like it would be pin cite 185 or between 185 and 186, okay? Does that help, your Honor?

THE COURT: Yeah, I'm there.

MR. LIPARI: So there, the Court indicates

"Plaintiff points out that the FDA publishes adverse events and MDRs in a public, searchable database called the Manufacturer and User Facility Device Experience, MAUDE, which physicians and the general public may access, etc. Thus Plaintiff argues that the Defendant's failure to timely report to the FDA led to a violation in state law in that the Defendants also did not exercise reasonable care in informing the medical community of known risks." That is within the context of the express preemption section. The Court then indicates that, "In view of that reporting, it's parallel, not different or in addition to."

That was part one of my argument. I'm sorry, go ahead.

THE COURT: I'm going to submit to you that that is somewhat tortured logic. To, essentially, I look at this, the *Rosen* decision, as though the Court was trying to recognize under New York State law that there is a same requirement that basically suing under state law for failure to warn is not adding or it's parallel to the requirements under federal law and that is just not the case.

MR. LIPARI: Okay, your Honor, so it's our contention --

THE COURT: Let me just say one more thing. Because there is no requirement under state law that you make a

report of an adverse event to the FDA.

MR. LIPARI: So, your Honor, I think that the Court essentially connects those dots and it's not tortured logic, in our estimation, and that is because of its reliance of the *Bee case and the Baker vs. St. Agnus* case, which it references specifically in its decision. I can point to that in a moment. And essentially, here is the point. If you look at the cases, especially *Baker vs. St. Agnus*, that is a Second Department New York State case from 1979, and just talks about strict liability law, failure to warn New York State juris prudence. And that court indicates that a manufacturer has a duty to take steps as are reasonably necessary to bring adverse event knowledge to the attention of the medical profession. So, your Honor, and that was first articulated, as we just stated, in *Baker vs. St. Agnus.* And thereafter, there is a nice recitation of it and explanation of it by the Eastern District of New York in *Bee*, which is B-e-e, Eastern District 2014. And there the Court has clearly articulated that that is exactly what New York State law requires. So, you know, it's our contention, and, frankly, it's the reasoning, which we would argue is not tortured, in the *Rosen* case. Under federal law, adverse events must be reported within 10 days, given the MAUDE system reporting adverse events and thus complying with federal law is the very way to discharge one's duty under state

court law, which, as *Bee* and *Baker* indicate, are taking steps that are reasonably necessary to bring adverse event knowledge to the attention of the medical profession.

THE COURT: If you get past express preemption, then you have the implied preemption argument and the causation argument that B&L is focused on. Why don't you focus on that argument?

MR. LIPARI: Your Honor, it's essentially the flip side of the same coin. And the quote that was attributed to the *Riley* case, we briefed it, that's fine. That Plaintiff must sue for conduct that violates the FDCA, but not because of conduct that violates FDCA. And, your Honor, that is precisely what we are doing here. We're suing because there was underreporting, which was in violation of that particular CFR provision. And by virtue of doing that, the manufacturer was not taking steps reasonably necessary to bring adverse event knowledge to the attention of the medical profession. And so, that line of implied preemption cases, especially Buckley -- *Buckman*, rather, they are completely inapposite and are very factually distinguishable from the case here. In *Buckman*, it's not a controversial proposition. Plaintiff was attempting a free-standing federal cause of action based on nothing but the violation of FDA regs. There was no underlying state court action that was even tied in. It was, you violated the FDA

regs, and, therefore, you're liable. And that is really a perfect example of when claims are impliedly preempted. Here, Plaintiff is not bringing a cause of action, you know, essentially saying that the FDCA gives Plaintiff a private right of action and now they are suing under the FDCA. We're suing only under the state tort juris prudence or statute or cause of action, which is perfectly articulated by the court in *Rosen*.

THE COURT: What about the causation argument? Your focus seems to be, well, if the Defendant complied with its federal obligations and made the report to the FDA, then, by definition, the medical professional who needed to be warned under state law would have ultimately been warned, but that isn't a duty flowing directly from the Defendant to the medical professional under the federal law requirements. It's a state law requirement, but that is arguably preempted by any federal law.

MR. LIPARI: Well, your Honor, the duty flows to the doctor.

THE COURT: But it's not a duty flowing from this defendant to the doctor.

MR. LIPARI: You're right.

THE COURT: The duty from this defendant flows to the FDA.

MR. LIPARI: Understood, your Honor. But this defendant has a duty, under the FDA regulations and under state court law, to warn the medical community.

THE COURT: No, it doesn't. That is the whole point. This defendant has a duty to warn the FDA. The FDA then has certain mechanisms in place to provide information to the medical community. But this defendant doesn't have any duty to warn the medical professional. It's the FDA and the FDA's database, and what the FDA decides to do with that database.

MR. LIPARI: We agree that the Defendant has a duty to warn or bring the adverse reports to the FDA's attention, we agree with that. However, we would disagree with your Honor's statement just a moment ago that they don't also have a duty to warn the medical community. And respectfully, Plaintiff's submit that was articulated in the *Bee* case and *Baker* case, and they have a responsibility to bring this to the FDA and that is to bring to the medical community.

THE COURT: Isn't there another purpose? Bringing these adverse events to the attention of the FDA serves multiple purposes? One could be because the FDA has the database, the MAUDE database, that provides these disclosures to the medical community. But another purpose could be for FDA regulation and to ensure the FDA is regulating these devices

and is updated on any new information that pertains to the devices. I'm sure those are just two of the various purposes for why the FDA has these regulations in the first place. But how the FDA decides to disseminate that information doesn't -- how does that transform, in other words, how does what the FDA decides to do with the information transform the Defendant into having a duty under federal law to warn the medical profession?

MR. LIPARI: Okay. Your Honor, we would suggest as follows. So, first of all, and I don't mean to keep beating this drum, but, again, under state tort law, their duty is to take steps that are reasonably necessary to bring reporting to the attention of the medical profession. Okay. One step that is reasonably necessary is simply to comply with federal law. And then there was an argument within Bausch & Lomb's brief that, well, there is not an automatic reporting to MAUDE. It's not a foregone conclusion that there is reporting to MAUDE. But first, this is the reasonably necessary step that needs to be taken to disseminate this to the medical community through the FDA. And, moreover, as a practical matter, this is what the FDA does. The FDA makes this publically available through the MAUDE system.

THE COURT: So, I take it a jury instruction in this case, for instance, would not be a typical failure to warn under state law, because there is other -- in other words, one

could argue that there are much more effective reasonable steps that a manufacturer could take to warn the medical community other than reporting it to some third-party federal regulatory agency.

MR. LIPARI: Your Honor, this is how they are reported. The whole purpose of the reporting requirement and the reporting regiment and the whole purpose of MAUDE, if one looks at the FDA's statement on MAUDE, is to disseminate this to the public and medical community and other interested individuals.

THE COURT: What about if there was no federal preemption, though? Under state law would there be any other duty on the part of the Defendant that the Plaintiff would be arguing that the manufacturer had to comply with here in terms of warning the medical professional?

MR. LIPARI: Minimal steps that are reasonable to alert the medical community.

THE COURT: Isn't there a state database or no? In other words, there is no state, under New York State law, the Department of Health doesn't have any kind of database that would collect this information?

MR. LIPARI: Your Honor, it's our understanding that this is a class 3 medical device, and as part of the regulations --

THE COURT: I'm not talking about this device in particular. You have a failure to warn cause of action against a manufacturer under state law that -- and there isn't any preemption argument. Wouldn't the Plaintiff be contending that the duty on the part of that defendant to warn would be far more than just notifying the FDA about any adverse events?

MR. SMULIAN: May I answer that one?

THE COURT: Well, let's hear from Mr. Lipari first.

MR. LIPARI: Well, your Honor, is there a state counterpart database? Not to my knowledge, your Honor. But beyond that, it would be our contention that the minimal duty, the minimum duty is set forth in those two cases, *Bee* and *Baker*, and, frankly, it coincides perfectly and parallels Defendant's obligation under federal law and that is to report adverse events. And it necessarily follows that when you report those adverse events, which you're obligated no do under federal law, it's put into a database and the medical community becomes aware of it. It coincides perfectly, it parallels perfectly, and that wasn't done here. We have several incidents of adverse reporting or, rather, underreporting.

THE COURT: Anything else, Mr. Lipari?

MR. LIPARI: Certainly. Just a few points, your Honor.

THE COURT: Sure.

MR. LIPARI: So, my adversary indicated that it stretches credulity and defies credulity and almost to the breaking point of how much time elapsed between the time of events that were underreported and the surgery. And it's our contention that is a red herring because, you know, the time that elapsed is, frankly, of no moment. It's about the number of adverse events making an impact on the doctor's decision to recommend the product and having a conversation with the patient. It's all encompassed in the MAUDE database. It doesn't matter if it's from 2011 or 2014. Defendant sort of characterizes it as, well, this doctor has to search all the way back and all these years elapsed. It's housed under one MAUDE database, which, arguably, arms the Defendant or rather arms the doctor with knowledge so that he can have a conversation with his patient about doing a risk/benefit analysis.

THE COURT: Anything else?

MR. LIPARI: I would just say, your Honor, that the issue of subject matter jurisdiction, which your Honor raised at the outset, is a threshold issue.

THE COURT: It is. I'm going to give you all some cites before we leave here today of the cases that we found that were raising a concern on my part, but go ahead.

MR. LIPARI: Right. So, again, it's our position it's a threshold issue, which should be decided, given that we've characterized it as a threshold issue, first, before we get into any of the substantive issues.

THE COURT: Okay. Thank you. You wanted to respond and maybe respond to the argument about the MAUDE database?

MR. SMULIAN: That too. I'll jump around, I apologize, your Honor.

THE COURT: That's okay.

MR. SMULIAN: As a starting point, I appreciate that Plaintiff's counsel has picked up on your Honor's potential scepticism of subject matter jurisdiction, but the fact is, and you raised it before --

THE COURT: He also didn't like my reference to the tortured logic in *Rosen*.

MR. SMULIAN: And he didn't make a motion to remand.

THE COURT: But that is irrelevant, you know, because I have to determine whether or not I have subject matter jurisdiction.

MR. SMULIAN: Absolutely, I understand it's not waivable, but just in terms of Plaintiff's taking up the cause.

THE COURT: It doesn't matter, though.

MR. SMULIAN: I know. A couple of things, just jumping around. The Plaintiff's conception of the duty under New York law of a manufacturer that he referred to from *Baker* and the *Baker vs. St. Agnus* and the *Bee* case, those are drug cases, and those drug cases did not exist in the context of -- there was nothing in the decisions about federal preemption. The question that your Honor was asking, and this is important, and was asking the Plaintiff, in the absence of preemption, what would the Plaintiff's claim be? The Plaintiff's claim would be that the labeling was insufficient.

THE COURT: But the labeling to the physician.

MR. SMULIAN: That the labeling that accompanies every medical device, that is the failure to warn. The fact is, they can't make that claim here under *Riegel* and all of the cases that follow *Riegel,* they can't say there was a failure in your labeling. This is all a tortured exercise to claim that there were risks that were not on the labeling that somehow we owed a duty to warn.

Going to the question of whether a parallel duty exists. There is a case, *Wolicki-Gables vs. Arrow*, it is an Eleventh Circuit case from 2011, and it explains the requirement like this or parallel claim. It says, "State and federal requirements are not generally equivalent if a manufacturer could be held liable under the state law without

having violated the federal law." Here, I mean --

THE COURT: That is clearly the case here.

MR. SMULIAN: Right. So they are not genuinely -- I think that concept.

THE COURT: I mean, state law, as you indicated, I mean, you would have the additional requirement to have a warning label or take reasonable steps. But, I mean, you've got to define it more specifically than just "reasonable steps." I mean, any negligence theory is reasonableness. And under that line of thinking, you would never have federal preemption.

MR. SMULIAN: Right.

THE COURT: So reasonable steps, under state law, encompasses a broad array of activity. Whereas, federal law, it's you have to provide a report of adverse events to the FDA.

MR. LIPARI: Your Honor, can I make one point? I think that I mentioned phraseology from the *Rosen* case at the outset, but I should emphasize it here. That is continuing obligation or continuing duty here. I think *Rosen* also focused on that. When you become aware of an adverse report, you have a continuing obligation, under state law, to warn members of the medical community. And that, also, that continuing obligation, also parallels the FDCA requirement that adverse reports, essentially, be reported to the FDA so they can put it

on the MAUDE system.

MR. SMULIAN: It doesn't parallel it.

THE COURT: I cut you off and then was turning to Mr. Lipari. Any other points that you wanted to make?

MR. SMULIAN: One final one with regard to the implied preemption and the idea that *Buckman* is limited to precluding a stand-alone fraud on the FDA claim is not true, both because of the cases, and there are many of them we cited in our brief, including cases from the Eleventh Circuit and even more recently from the Supreme Court in the case of *Pliva vs. Mensing*, 564 U.S. 604 on page 619. *Pliva vs. Mensing* referred to *Buckman* and was cited for the proposition specifically that, quote, "Federal drug and medical device laws preempted the state law tort claim based on the failure to properly communicate with the FDA." *Buckman* has a much broader scope than merely precluding fraud on the FDA claims. *Buckman* precludes claims that are based on attempt to privatize any portion of the FDCA.

THE COURT: Okay. Final point.

MR. LIPARI: Sure, your Honor, thank you. So, let me just say, it appears, distilling this to its essence, Defendant is taking the position that Judge Wexler got it right and that the *Rosen* case was decided incorrectly. And the Defendant has indicated that the weight of authority is on his

side. I would just say, if you do a one-for-one comparison, there is actually a logical analysis that cites to tort law and tort juris prudence in the *Rosen* case that is absent from the *Pearsall* case. And finally, Defendant has gone outside the Second Circuit and he has pointed to a hodge-podge of various cases in various circuits, but the issue was decided correctly in *Rosen*. And within the last two weeks, one case that has been reported, and it's from the Third Circuit, but --

THE COURT: I saw it.

MR. LIPARI: The *Bull vs. St. Jude?*

THE COURT: The jury verdict?

MR. LIPARI: I was referring to a motion to dismiss where they go through the very analysis in the Third Circuit. I could give your Honor the cite.

THE COURT: Could you give me the cite?

MR. LIPARI: Bull vs. St. Jude, 2018 U.S. District Lexis 115730.

THE COURT: 115730?

MR. LIPARI: Correct, your Honor. And it was essentially -- and I'll be very, very quick. The failure to warn survived the motion to dismiss scrutiny, this involved Riata Lead, which are a Class 3 medical device. The Court ruled that Plaintiff's state law claim identifies a state duty to warn physicians of risks inherent to medical devices through

reporting, which makes its way onto the MAUDE system, and that is parallel to Defendant's duty to comply with adverse reporting requirements.

THE COURT: Okay. That is not cited in your papers because it was just --

MR. LIPARI: Correct, your Honor. I think Lexis just published it within the last couple of days.

THE COURT: Let me give you the cites that have caused me -- and this is by no means comprehensive, it was based on mine and my law clerk's research leading up to the subject matter jurisdiction. There is the Connecticut case that I cited at the outset. I would note as well on page 34 of the Connecticut decision, the case the Court distinguishes *Bowdrie vs. Sun Pharmaceutical Industries*, the Eastern District of New York case from 2012 that Bausch & Lomb cited in its Notice of Removal, and, among other things, it was a pre *Gunn* case, that is what the court says, and then it goes on to distinguish it. There is a case from the Eastern District of Virginia, it's *Carmine vs. Poffenbarger*, 154 F. Supp. 3d 309, Eastern District of Virginia from 2015. Case from the Western District of Texas, *Maher vs. Vaughn, Silverberg & Associates*, 95 F. Supp. 3d 999, Western District of Texas from 2015. An unreported case from the Eastern District of Kentucky, *Newsome vs. Bayer Corporation*, 2018 Westlaw 1906103, that is 1906103

from April 23, 2018, and it involves a failure to conform with FDA post-marketing monitoring requirements of a Class 3 medical device. And the Court held that reporting requirements do not implicate substantial federal issues. Preemption does not alone raise a substantial federal issue. And there is another Texas case, this is *Windle vs. Synthes USA Products*, 2012 Westlaw 1252550 from April 13th, 2012. And then *In Re Vioxx Products Liability Litigation*, 843 F. Supp 2d 654, Eastern District of Louisianna from January 3, 2012. Court held it was not substantial because even if there is a violation of FDA disclosure requirements, the federal question would be resolved in the context of whether the conduct was a violation of state law.

I will say, based on my review -- and actually, just to make the record complete, what initially led me down this path was a case from California, which may have been cited by somebody in the papers, it was *Sangimino vs. Bayer Corp.*, 2017 Westlaw 2500904, this is Northern District of California from -- I've written on the month -- I think June 9th, 2017, where the Court says that "It is settled law that you cannot remove to Federal Court on the basis of a federal defense, including federal preemption." I appreciate here that B & L is arguing this isn't a defense that has gotten us here, it's the claim that is based on the violation of the reporting

requirements to the FDA. But there is still state law causes of action. And based on my reading of these cases, the fact that you're relying on a duty to report under federal law to craft a state law cause of action would not constitute a substantial question of federal law so as to get you into federal court. And that is why I went back, and I think I went -- actually had to go onto PACER to look at both *Pearsall* and *Rosen*, how those cases ended up in federal court, and my recollection is they are both diversity cases. So this is a threshold issue that we're going to have to sort through before I get to the other issues.

MR. LIPARI: Your Honor, so, and perhaps I'm sort of jumping ahead, but so does your Honor want the parties to brief this threshold issue?

THE COURT: Yes. And let's set a briefing schedule. I guess, I wanted to give you the cases that I had looked at so that if you can distinguish them, go ahead and do that. These are the cases that I was looking at that was leading me to the potential conclusion.

MR. LIPARI: And, your Honor, so this, the briefing on the motion to dismiss then should be held in abeyance holding the briefing on the matter of subject matter jurisdiction?

THE COURT: Well, I'm not going to make a decision

on the motion to dismiss until I get through this issue. I wasn't going to require any more briefing on the motion to dismiss. So let's talk about process and timing. You know, my view is that I should hear first from Bausch & Lomb, and then give the Plaintiff an opportunity to respond to that, and then give you an opportunity to reply.

MR. SMULIAN: That would -- we would appreciate that, your Honor.

THE COURT: Any issue with that, Mr. Lipari? I mean, it's Bausch & Lomb's burden to establish jurisdiction since that is the entity that removed this into federal court.

MR. LIPARI: No, your Honor.

THE COURT: How much time would you be requesting to brief this issue?

MR. SMULIAN: Three weeks?

THE COURT: Okay. So today is the 27th. So by September 17th, Bausch & Lomb needs to file a memo addressed to this issue. I'll give the Plaintiff three weeks to respond. Does that work?

MR. LIPARI: Thank you, your Honor.

THE COURT: That will take you to October 8th. And then I'll give Bausch & Lomb -- I'll give you 10 days for any reply. So we'll push it out to the end of the week, October 19th for a reply.

MR. SMULIAN: Thank you, Judge.

THE COURT: You're welcome. We'll issue a text order just confirming those deadlines.

MR. SMULIAN: And then --

THE COURT: I wasn't -- if I, after receiving that briefing, if I feel the need for oral argument, I'll notify you. I hate to -- I know most of you, at least, are coming from out of town. I don't want to have to make you do that again. Maybe we can do it by telephone if I have specific questions on the subject matter jurisdiction issue. But I'll reserve on that issue until I see the briefing from both parties. Again, I did not have an opportunity to exhaustively look into this issue. Neither one of you have briefed the issue, other than, I suppose, what is set forth in the Notice of Removal, but I do have some concerns about whether or not I have subject matter jurisdiction. So, that is where things stand. So, otherwise, I'll reserve on the motion to dismiss. And as I said, I won't be resolving that until I sort through the subject matter jurisdiction issue. So, if after reviewing the briefing, conclude I do have subject matter jurisdiction, then I'll be issuing a decision that, point one, will address jurisdiction, and then dealing with the motion to dismiss. But if I decide I don't have subject matter jurisdiction, then I'll be issuing a decision remanding this to state court. All

right? Any questions from the Plaintiff's perspective?

MR. LIPARI: No, your Honor, thank you.

THE COURT: All right. From Bausch & Lomb's perspective?

MR. SMULIAN: No, Judge. Thank you.

THE COURT: Anything else from the other Defense Counsel?

MR. PAULINO: No, your Honor.

MR. VONWALDOW: No, your Honor. Thank you very much.

THE COURT: And I don't know, you're welcome to, I wasn't anticipating that you would brief on behalf of your clients this issue of jurisdiction. But it pertains to codefendants, too. So, if, in fact, you do want to brief the issue, you would have the same deadlines as Bausch & Lomb does. Okay?

MR. VONWALDOW: Sounds good, thank you.

THE COURT: All right. Thank you very much, everybody. Safe travels back.

MR. SMULIAN: Thank you, Judge.

* * *

CERTIFICATE OF REPORTER

I certify that the foregoing is a correct transcript of the record of proceedings in the above-entitled matter.

S/ Karen J. Bush, RPR

Official Court Reporter